STATE OF SOUTH CAROLINA,	IN THE COURT OF COMMON PLEAS
COUNTY OF FLORENCE	
KELLI BAUGH and JUSTIN BAUGH, Plaintiff,	SUMMONS
vs.	FILE NO. 11-CP- 21-133
BAYER CORPORATION, BAYER HEALTHCARE, LLC, BAYER PHARMACEUTICALS CORPORATION, BAYER HEALTHCARE PHARMACEUTICALS, INC., BERLEX LABORATORIES, INC., and BERLEX, INC., Defendant.	

TO THE DEFENDANT ABOVE-NAMED:

YOU ARE HEREBY SUMMONED and required to answer the complaint herein, a copy of which is herewith served upon you, and to serve a copy of your answer to this complaint upon the subscriber, at the address shown below, within thirty (30) days after service hereof, exclusive of the day of such service, and if you fail to answer the complaint, judgment by default will be rendered against you for the relief demanded in the complaint.

Florence, South Carolina

Dated: January 21, 2011

Plaintiff/Attorney for Plaintiff

Address: Carmen S. Scott, Esquire
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STATE OF SOUTH CAROLINA
COUNTY OF FLORENCE

IN THE COURT OF COMMON PLEAS
FILE NO: 11-CP-21 - 133

KELLI BAUGH and JUSTIN BAUGH,

Plaintiffs,

v.

BAYER CORPORATION, BAYER HEALTHCARE, LLC, BAYER PHARMACEUTICALS CORPORATION, BAYER HEALTHCARE PHARMACEUTICALS, INC., BERLEX LABORATORIES, INC., and BERLEX, INC.,

Defendants.

COMPLAINT AND JURY DEMAND

COME NOW, Plaintiffs Kelli Baugh and Justin Baugh, husband and wife, by and through the undersigned counsel, hereby allege against Bayer Corporation, Bayer Healthcare, LLC, Bayer Pharmaceuticals Corporation, Bayer Healthcare Pharmaceuticals, Inc., Berlex Laboratories, Inc. and Berlex, Inc. the following:

PARTIES AND CITIZENSHIP

1. Plaintiffs Kelli Baugh (hereinafter "Ms. Baugh") and Plaintiff Justin Baugh (collectively "Plaintiffs") are, and at the times mentioned in this Complaint were, husband and wife.

2. The Plaintiffs are and were at the times mentioned in this Complaint residents of Florence, South Carolina, and are citizens of the State of South Carolina.

3. Defendant Bayer Corporation (hereinafter "Bayer" or "Defendant") is, and at all times relevant was, a corporation organized under the laws of the State of Indiana with its headquarters and principal place of business at 100 Bayer Rd., Pittsburgh, Pennsylvania 15205.

4. Defendant Bayer Healthcare LLC, is, and at times relevant was, a limited liability corporation organized under the laws of the State of Delaware with its headquarters and principal place of business at 100 Bayer Road, Pittsburgh, Pennsylvania 15205.

5. Defendant Bayer Healthcare, LLC is wholly owned by Defendant Bayer Corporation.

6. Defendant Bayer Pharmaceuticals Corporation is, and at times relevant was, a corporation organized under the laws of the State of Delaware with its headquarters and principal place of business at 1400 Morgan Lane, West Haven, Connecticut.

7. On or around January 1, 2008, Defendant Bayer Pharmaceuticals Corporation merged into Defendant Bayer Healthcare Pharmaceuticals, Inc.

8. Defendant Bayer Healthcare Pharmaceuticals Inc., is and at times relevant was, a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 340 Changebridge Road, P.O. Box 1000, Montville, New Jersey 07045-1000.

9. Defendant Bayer Healthcare Pharmaceuticals, Inc. was formerly known as Berlex, Inc., which was formerly known as Berlex Laboratories, Inc., and is the same corporate entity as Berlex, Inc. and Berlex Laboratories, Inc.

10. Defendant Bayer Healthcare Pharmaceuticals Inc. is the holder of the approved New Drug Application ("NDA") for contraceptive device Mirena.

11. Defendants Berlex Laboratories, Inc. and Berlex, Inc. are, and at all times relevant were, foreign corporations with their headquarters and principal places of business at Montville, New Jersey and with a post office address of P.O. Box 1000, Montville, New Jersey, 07045 and places of business located at 6 West Belt Road, Wayne, New Jersey 07470.

12. Defendants Berlex Laboratories, Inc. and Berlex, Inc. were integrated into Bayer HealthCare AG and operate as an integrated specialty pharmaceuticals business under the new name, Defendant Bayer Healthcare Pharmaceuticals, Inc.

13. Bayer Corporation is in the business of designing, manufacturing, and marketing prescription drugs and women's healthcare products, including the intrauterine contraceptive system, Mirena.

14. Bayer Corporation does business in South Carolina through the sale of Mirena and other prescription drugs in the state.

15. At all times alleged herein, Defendants include and included any and all parents, subsidiaries, affiliates, divisions, franchises, partners, joint venturers, and organizational units of any kind, their predecessors, successors and assigns and their officers, directors, employees, agents, representatives and any and all other persons acting on their behalf.

16. At all times herein mentioned, each of the Defendants was the agent, servant, partner, predecessors in interest, aider- and abettor, co-conspirator and joint venturer of each of the remaining Defendants herein and was at all times operating and acting with the purpose and scope of said agency, service, employment, partnership, conspiracy and joint venture.

17. At all times relevant, Defendants were engaged in the business of developing, designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing into interstate commerce throughout the United States, either directly or indirectly through third parties, subsidiaries or related entities, the contraceptive device, Mirena.

FACTS

18. Plaintiffs incorporate by reference all other paragraphs of this complaint as if fully set forth herein, and further allege as follows:

19. Mirena is an intrauterine contraceptive system made of flexible plastic that is inserted by a healthcare provider during an office visit.

20. The federal Food and Drug Administration (FDA) approved Defendants' New Drug Application for Mirena in December 2000. Today, more than 2 million women in the United States use Mirena. It has been used by more than 15 million women worldwide.

21. The system releases levonorgestrel, a synthetic progestogen, directly into the uterus for birth control. Defendants admit "[i]t is not known exactly how Mirena works," but provide that Mirena may thicken cervical mucus, thin the uterine lining, inhibit sperm movement and reduce sperm survival to prevent pregnancy.

22. The Mirena intrauterine system (IUS) is designed to be placed within seven (7) days of the first day of menstruation and approved to remain in the uterus for up to five years. If continued use is desired after five years, the old system must be discarded and a new one inserted.

23. The package labeling recommends that Mirena be used in women who have had at least one child, suggesting that carrying a child to term may be complicated after Mirena use..

24. Mirena's label does not warn about spontaneous migration of the IUS, but only states that migration may occur if the uterus is perforated during insertion.

25. Clinical studies show . . . [mirena causes more perforations than other IUS?]

26. Defendants have a history of overstating the efficacy of Mirena while understating the potential safety concerns.

27. In or around December 2009, Defendants were contacted by the Department of Health and Human Services' Division of Drug Marketing, Advertising, and Communications (DDMAC) regarding a consumer-directed program entitled "Mirena Simple Style Statements

Program," a live presentation designed for "busy moms." The Simple Style program was presented in a consumer's home or other private setting by a representative from "Mom Central", a social networking internet site, and Ms. Barb Dehn, a nurse practitioner, in partnership with Defendants.

28. This Simple Style program represented that Mirena use would increase the level of intimacy, romance and emotional satisfaction between sexual partners. DDMAC determined these claims were unsubstantiated and, in fact, pointed out that Mirena's package insert states that at least 5% of clinical trial patients reported a decreased libido after use.

29. The Simple Style program script also intimated that Mirena use can help patients "look and feel great." Again, DDMAC noted these claims were unsubstantiated and that Mirean can cause a number of side effects, including weight gain, acne, and breast pain or tenderness.

30. The portion of the Simple Style script regarding risks omitted information about serious conditions, including susceptibility to infections and the possibility of miscarriage is a woman becomes pregnant on Mirena.

31. Finally, Defendants falsely claimed that Defendants' program falsely represented that the system required no compliance with a monthly routine.

32. Plaintiff Kelli Baugh is a 25 year-old nursing student.

33. Plaintiff's physician, Dr. Anu Chaudhry, inserted the Mirena system on November 1, 2005. While she suffered some mild discomfort and bleeding, neither Plaintiff nor Dr. Chaudhry had any reason to suspect that the Mirena perforated her uterus.

34. Following the Mirena insertion, Plaintiff self-checked the strings on the Mirena, finding them present.

35. At a follow-up visit in December 2005, Dr. Chaudhry performed a pelvic exam and confirmed with Plaintiff that the strings of the Mirena could still be felt, indicating to her that the IUD was properly placed.

36. In early 2006, Plaintiff contacted Dr. Chaudhry's office informing her that she was experiencing pain and could no longer feel her strings. Dr. Chaudhry informed her that she likely cut the strings too short and that she should come in if her pain became severe.

37. In late 2006, early 2007, Plaintiff began experiencing pain during intercourse. She saw a different OB/Gyn practice in March 2007 at which point Dr. William Goldstein performed an ultrasound in office and told Plaintiff the Mirena was still in the uterus although it could not be visualized completely. As Plaintiff's insurance would not pay for exploratory surgery, and as this physician did not believe migration had occurred, Plaintiff kept the Mirena inserted.

38. Plaintiff returned to Dr. Chaudhry's office on January 23, 2008 complaining of pain. Dr. Chaudhry conducted an ultrasound and discovered that Plaintiff's Mirena had "dislodged."

39. A CT scan performed on January 24, 2008, confirmed that the Mirena was extrauterine and present in the right lower quadrant. The Mirena had migrated from her uterus into her pelvic cavity.

40. On January 28, 2008, Ms. Baugh underwent laparoscopic removal of the Mirena which was found to be imbedded in her omentum. Dr. Chaudhry commented on the amount of fibrous scar tissue present during the surgery.

41. Plaintiff did not heal well following her Mirena removal. The continued to experience discomfort and intercourse was painful.

42. Plaintiff became pregnant in February 2009 and presented to Dr. Tatum McLeod OB/Gyn Associates on March 17, 2009 for an initial pregnancy visit. She delivered in November 2009.

43. On December 23, 2009, Ms. Baugh presented to Dr. Tatum at McLeod OB/Gyn Associates with acute pain during menstruation and intercourse.

44. She again saw Dr. Tatum at McLeod OB/Gyn on February 18, 2010 for extremely severe pelvic pain thought to be secondary to adhesions caused by the Mirena uterine perforation.

45. Dr. Tatum explained that Plaintiff could treat her problems with pain management or could undergo a total hysterectomy to alleviate her continued pain.

46. On March 16, 2010, Plaintiff underwent a procedure to remove her uterus, cervix, fallopian tubes and one ovary.

47. Images from the surgery pointed to endometriosis as a cause of Plaintiff's pain.

48. Endometriosis is a condition in which cells that line the uterus escape to other areas of the body and cause pain. When the Mirena perforated Plaintiff's uterus, uterine cells escaped the uterus and attached to the scar tissue on the uterus.

49. Dr. Tatum opined by letter that Plaintiff's adhesions were partially responsible for her post-perforation symptoms that led to her hysterectomy.

50. Since the time of Plaintiff's hysterectomy, her remaining ovary has failed to produce enough hormones and Plaintiff is beginning to experience the effects of menopause at age 25.

AS A FIRST CAUSE OF ACTION:
DEFECTIVE DESIGN – S.C. Code § 15-73-10 *et. seq.*

51. Plaintiffs incorporate by reference all other paragraphs of this complaint as if fully set forth, and further allege as follows:

52. Defendants were and are engaged in the business of selling Mirena in the State of South Carolina.

53. The Mirena manufactured, marketed, promoted and sold by Defendants was expected to, and did, reach Plaintiff Kelli Baugh without substantial change in the condition in which it was sold.

54. Defendants have introduced a product into the stream of commerce which is dangerous and unsafe in that the harm of Mirena outweighs any benefit derived therefrom. The unreasonably dangerous nature of Mirena caused serious harm to Plaintiff Kelli Baugh.

55. Defendants manufactured, marketed, promoted and sold a product that was not merchantable and/or reasonably suited to the use intended, and its condition when sold was the proximate cause of the injuries sustained by the Plaintiff Kelli Baugh.

56. As a direct and proximate cause of Plaintiff Kelli Baugh's use of Mirena, she had to undergo surgical removal of the IUS, developed severe paid from adhesions caused by the perforation, and had to have a hysterectomy.

57. Defendants placed Mirena into the stream of commerce with wanton and reckless disregard for the public safety.

58. Defendants knew and, in fact, advertised and promoted the use of Mirena despite their failure to test or otherwise determine the safety and efficacy of such use. As a direct and proximate result of the defendants' widespread promotional activity, physicians began commonly prescribing this product as safe and effective.

59. Despite the fact that evidence existed that the use of Mirena was dangerous and likely to place users at serious risk to their health, Defendants failed to disclose and warn of the health hazards and risks associated with the Mirena and in fact acted to deceive the medical community and public at large, including all potential users of Mirena by promoting it as safe and effective.

60. Defendants knew or should have known that physicians and other healthcare providers began commonly prescribing this product as a safe and effective contraceptive despite its lack of efficacy and potential for serious permanent side effects.

61. There are contraceptives on the market with safer alternative designs in that they provide equal or greater efficacy and far less risk.

62. As a direct and proximate result of one or more of these wrongful acts or omissions of the Defendants, Plaintiff Kelli Baugh suffered profound injuries, required and continues to require medical treatment, and incurred and continues to incur medical and hospital expenses.

WHEREFORE, Plaintiffs demand judgment against each Defendant for compensatory, statutory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems appropriate pursuant to the common law and statutory law.

AS A SECOND CAUSE OF ACTION:
NEGLIGENCE

63. Plaintiffs incorporate by reference all other paragraphs of this complaint as if fully set forth, and further allege as follows:

64. Upon information and belief, Defendants failed to use reasonable care in designing Mirena in that they:

a. failed to properly and thoroughly test Mirena before releasing the drug to market;

b. failed to properly and thoroughly analyze the data resulting from the pre-marketing tests of Mirena;

c. failed to conduct sufficient post-market testing and surveillance of Mirena;

d. designed, manufactured, marketed, advertised, distributed, and sold Mirena to consumers, including Plaintiff, without an adequate warning of the significant and dangerous risks of Mirena and without proper instructions to avoid the harm which could foreseeably occur as a result of using the drug;

e. failed to exercise due care when advertising and promoting Mirena; and

f. negligently continued to manufacture, market, advertise, and distribute Mirena after Defendants knew or should have known of its adverse effects.

65. A reasonable manufacturer would or should have known that its risks created by Mirena are unreasonably greater than that of other contraceptives and that Mirena has no clinical benefit over such other contraceptives that compensates in whole or part for the increased risk.

66. As a direct and proximate result of one or more of these wrongful acts or omissions of the Defendants, Plaintiff Kelli Baugh suffered profound injuries, required and continues to require medical treatment, and incurred and continues to incur medical and hospital expenses.

WHEREFORE, Plaintiffs demand judgment against each Defendant for compensatory, statutory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems appropriate pursuant to the common law and statutory law.

AS A THIRD CAUSE OF ACTION:
FAILURE TO WARN

67. Plaintiffs incorporate by reference all other paragraphs of this complaint as if fully set forth, and further allege as follows:

68. Mirena is a defective and therefore unreasonably dangerous product, because its labeling fails to adequately warn consumers and prescribers of, among other things, the risk of migration of the product post-insertion, development of endometriosis resulting from uterine perforation, or possibility that device complication may necessitate hysterectomy.

69. Defendants researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold, and otherwise released into the stream of commerce the pharmaceutical, Mirena, and in the course of same, directly advertised or marketed the product to consumers or persons responsible for consumers, and therefore had a duty to warn of the risks associated with the use of Mirena.

70. Mirena was under the exclusive control of Defendants and was unaccompanied by appropriate warnings regarding all of the risks associated with its use. The warnings given did not accurately reflect the risk, incidence, symptoms, scope or severity of such injuries to the consumer or physicians. The promotional activities of Defendants further diluted or minimized the warnings given with the product.

71. Defendants downplayed the serious and dangerous side effects of Mirena to encourage sales of the product; consequently, Defendants placed its profits above its customers' safety.

72. Mirena was defective and unreasonably dangerous when it left the possession of Defendants in that it contained warnings insufficient to alert Plaintiffs to the dangerous risks and reactions associated with it. Even though Defendants knew or should have known of the risks and reactions associated with Mirena, they still failed to provide warnings that accurately reflected the signs, symptoms, incident, scope, or severity of the risks associated with the product.

73. Plaintiff Kelli Baugh used Mirena as intended and as indicated by the package labeling or in a reasonably foreseeable manner.

74. Plaintiff could not have discovered any defect in Mirena through the exercise of reasonable care.

75. Defendants, as manufacturers of pharmaceutical drugs, are held to the level of knowledge of an expert in the field and, further, Defendants had knowledge of the dangerous risks and side effects of Mirena.

76. Plaintiff did not have the same knowledge as Defendants and no adequate warning was communicated to her physician(s).

77. Defendants had a continuing duty to warn consumers, including Plaintiff Kelli Baugh and her physicians, and the medical community of the dangers associated with Mirena, and by negligently and/or wantonly failing to adequately warn of the dangers associated with its use, Defendants breached their duty.

78. Although Defendants knew, or were reckless in not knowing, of the defective nature of Mirena, they continued to design, manufacture, market, and sell Mirena without providing adequate warnings and instructions concerning the use of Mirena so as to maximize sales and profits at the expense of the public health and safety, in knowing, conscious, and deliberate disregard of the foreseeable harm caused by Mirena.

79. As a direct and proximate result of one or more of these wrongful acts or omissions of the Defendants, Plaintiff Kelli Baugh suffered profound injuries, required and continues to require medical treatment, and incurred and continues to incur medical and hospital expenses.

WHEREFORE, Plaintiffs demand judgment against each Defendant for compensatory, statutory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems appropriate pursuant to the common law and statutory law.

AS A FOURTH CAUSE OF ACTION:
STRICT LIABILITY

80. Plaintiffs incorporate by reference all other paragraphs of this complaint as if fully set forth herein, and further allege as follows:

81. Defendants are manufacturers and/or suppliers of Mirena and are strictly liable to Plaintiffs for designing, creating, manufacturing, distributing, selling and placing Mirena into the stream of commerce.

82. The Mirena manufactured and/or supplied by Defendants was defective in design or formulation in that, when it left the hands of the manufacturer and/or suppliers, it was unreasonably dangerous, it was more dangerous than an ordinary consumer would expect and more dangerous than other contraceptives.

83. The Mirena was defective in design or formulation in that, when it left the hands of the manufacturer and/or suppliers, the foreseeable risks exceeded the benefits associated with the design or formulation.

84. Mirena was also defective due to inadequate warnings or instructions because the manufacturer knew or should have known that Mirena created, among other things, a risk of perforation and migration and associated infections or conditions and the Defendants failed to adequately warn of these risks.

85. Mirena was defective due to inadequate pre-marketing testing.

86. Defendants failed to provide adequate initial warnings and post-marketing warnings or instructions after the manufacturer and/or supplier knew or should have known of

the extreme risks associated with Mirena and continues to promote Mirena in the absence of those adequate warnings.

87. As a direct and proximate result of one or more of these wrongful acts or omissions of the Defendants, Plaintiff Kelli Baugh suffered profound injuries, required and continues to require medical treatment, and incurred and continues to incur medical and hospital expenses.

WHEREFORE, Plaintiffs demand judgment against each Defendant for compensatory, statutory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems appropriate pursuant to the common law and statutory law.

AS A FIFTH CAUSE OF ACTION:
BREACH OF IMPLIED WARRANTY

88. Plaintiffs incorporate by reference all other paragraphs of this complaint as if fully set forth herein, and further allege as follows:

89. Defendants marketed, manufactured, promoted, distributed and/or sold Mirena as safe for use by the public at large, including Plaintiff, who purchased Mirena. Defendants knew the use for which their product was intended and impliedly warranted the product to be of merchantable quality, safe and fit for use.

90. Plaintiff Kelli Baugh reasonably relied on the skill and judgment of the Defendants, and as such their implied warranty, in using Mirena.

91. Contrary to same, Mirena was not of merchantable quality or safe or fit for its intended use, because it is unreasonably dangerous and unfit for the ordinary purpose for which it was used.

92. As a direct and proximate result of one or more of these wrongful acts or omissions of the Defendants, Plaintiff Kelli Baugh suffered profound injuries, required and

continues to require medical treatment, and incurred and continues to incur medical and hospital expenses.

WHEREFORE, Plaintiffs demand judgment against each Defendant for compensatory, statutory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems appropriate pursuant to the common law and statutory law.

AS A SIXTH CAUSE OF ACTION:
PERSONAL INJURY – KELLI BAUGH

93. Plaintiffs incorporate by reference all other paragraphs of this complaint as if fully set forth, and further allege as follows:

94. Plaintiff Kelli Baugh's was inserted with Mirena manufactured by the Defendants on November 1, 2005.

95. The Mirena inserted into Plaintiff Kelli Baugh was in substantially the same form when inserted as it was when placed into the stream of commerce by the Defendants.

96. Plaintiff Kelli Baugh's Mirena was found to be dislodged in January 2008, after which point she underwent surgery to remove the device. The adhesions created by the Mirena perforation caused such pain that Plaintiff had to undergo a hysterectomy in March 2010.

97. The Mirena was a substantial contributing cause of the development of Plaintiff's gynecological problems leading to her hysterectomy.

98. Defendants' conduct, and/or their Mirena product, as set forth in any one, all, or a combination of the bases of liability identified above, substantially contributed to causing Plaintiff's medical problems.

99. Plaintiff Kelli Baugh was unaware, and did not have the capacity to be aware, of the connection between Mirena and perforation or migration after insertion at the time the Mirena was inserted.

100. As a result of her medical problems, Plaintiff Kelli Baugh:

a. Suffered severe pain;

b. Endured surgical removal of the Mirena system;

c. Underwent a total hysterectomy;

d. Received medical treatment, and will require additional medical treatment in the future;

e. incurred medical expenses and will incur additional medical expenses in the future; and

f. Lost the ability to ever bear children again.

101. As a direct and proximate result of one or more of these wrongful acts or omissions of the Defendants, Plaintiff Kelli Baugh suffered profound injuries, required and continues to require medical treatment, and incurred and continues to incur medical and hospital expenses.

WHEREFORE, Plaintiffs demand judgment against each Defendant for compensatory, statutory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems appropriate pursuant to the common law and statutory law.

AS A SEVENTH CAUSE OF ACTION:
BREACH OF EXPRESS WARRANTY

102. Plaintiffs incorporate by reference all other paragraphs of this complaint as if fully set forth and further alleges as follows:

103. The aforementioned manufacturing, designing, distributing, marketing, and promoting of Mirena were expressly warranted to be safe by Defendants for Plaintiff Kelli Baugh and members of the public generally. At the time of the making of these express warranties, Defendants had knowledge of the foreseeable purposes for which Mirena was to be

used and Defendants warranted Mirena to be in all respects safe, effective and proper for such purposes.

104. Mirena does not conform to these express warranties and representations because Mirena is not safe or effective and may produce serious side effects.

105. As a direct and proximate result of one or more of these wrongful acts or omissions of the Defendants, Plaintiff Kelli Baugh suffered profound injuries that required medical treatment and incurred medical and hospital expenses.

WHEREFORE, Plaintiffs demand judgment against Defendants for compensatory, statutory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems appropriate pursuant to the common law and statutory law.

AS A EIGHTH CAUSE OF ACTION:
NEGLIGENT MISREPRESENTATION

106. Plaintiffs incorporate by reference all other paragraphs of this complaint as if fully set forth and further alleges as follows:

107. Defendants, having undertaken the designing, manufacturing, marketing, distribution and/or promotion of Mirena, owed a duty to provide accurate and complete information regarding Mirena.

108. Defendants falsely represented to Plaintiff Kelli Baugh that Mirena was a safe and effective contraceptive option. The representations by Defendants were in fact false, as Mirena is not safe and is dangerous to the health of its users.

109. At the time the aforesaid representations were made, Defendants concealed from Plaintiff Kelli Baugh and health care providers information about the propensity of Mirena to cause great harm. Defendants negligently misrepresented claims regarding the safety and efficacy of Mirena despite the lack of information regarding same.

110. These misrepresentations were made by Defendants with the intent to induce Plaintiff Kelli Baugh to use Mirena, which caused his injury.

111. At the time of Defendants' misrepresentations and omissions, Plaintiff Kelli Baugh was ignorant of the falsity of these statements and reasonably believed them to be true.

112. Defendants breached their duties to Plaintiff Kelli Baugh by providing false, incomplete and/or misleading information regarding their product. Plaintiff Kelli Baugh reasonably believed Defendants' representations and reasonably relied on the accuracy of those representations when agreeing to treatment with Mirena.

113. As a direct and proximate result of one or more of these wrongful acts or omissions of the Defendants, Plaintiff Kelli Baugh suffered a profound injury that required medical treatment and incurred medical and hospital expenses.

WHEREFORE, Plaintiffs demand judgment against Defendants for compensatory, statutory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems appropriate pursuant to the common law and statutory law.

AS AN NINTH CAUSE OF ACTION:
FRAUDULENT MISREPRESENTATION

114. Plaintiffs incorporate by reference all other paragraphs of this complaint as if fully set forth and further alleges as follows:

115. Defendants, having undertaken the manufacturing, marketing, prescription, dispensing, distribution and promotion of Mirena described herein, owed a duty to provide accurate and complete information regarding Mirena.

116. Defendants fraudulently misrepresented material facts and information regarding Mirena including, but not limited to, its propensity to cause serious physical harm.

117. At the time of Defendants' fraudulent misrepresentations and omissions, Plaintiff Kelli Baugh was unaware and ignorant of the falsity of the statements and reasonably believed them to be true.

118. Defendants knew this information to be false, incomplete and misleading information.

119. Defendants intended to deceive and mislead Plaintiff Kelli Baugh so that he might rely on these fraudulent misrepresentations.

120. Plaintiff Kelli Baugh had a right to rely on and did reasonably rely upon Defendants' deceptive, inaccurate and fraudulent misrepresentations.

121. As a direct and proximate result of one or more of these wrongful acts or omissions of the Defendants, Plaintiff Kelli Baugh suffered profound injuries that required medical treatment and incurred medical and hospital expenses.

WHEREFORE, Plaintiffs demand judgment against Defendants for compensatory, statutory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems appropriate pursuant to the common law and statutory law.

AS A TENTH CAUSE OF ACTION:
Violation of South Carolina Unfair Trade Practices Act
S.C. Code Annotated § 39-5-10 *et seq.*

122. Plaintiffs incorporate by reference all other paragraphs of this complaint as if fully set forth and further alleges as follows:

123. Defendants' acts constitute unfair trade practices in that:

a. Defendants engaged in unconscionable commercial practice through deception, fraud and making false promises and misrepresentations.

b. Defendants marketed and promoted Mirena as safe and effective in the absence of any long-term studies confirming safety or efficacy.

c. Defendants failed to disclose to the FDA and the public knowledge of the health hazards posed by the usage of Mirena.

d. Defendants downplayed and understated the health hazards and risks associated with the use of Mirena.

e. Defendants utilized the methods and manner by which they undertook to create a market environment, which fostered the aggressive dispensation of this product.

f. In connection with the sale and advertisement of Mirena, Defendants:

i. engaged in knowing concealment, suppression and omission of material

ii. facts regarding the health hazards created by the use of the product.

g. Defendants marketed their product as being of a standard that it was not.

124. Defendants' unlawful sale and advertising practices were specifically designed to induce the public to seek out, obtain prescriptions, purchase and administer this product, which acts are capable of repetition and were repeated.

125. As a result of Defendants' consumer fraud, Plaintiff Kelli Baugh has suffered ascertainable losses via the cost of Defendants' Mirena, medical and hospital expenses, and other costs.

126. As such, Plaintiff Kelli Baugh is entitled to recover his actual damages sustained, treble damages, attorneys' fees, reasonable costs of suit and punitive damages.

127. As a direct and proximate result of one or more of these wrongful acts or omissions of the Defendants, Plaintiff Kelli Baugh suffered profound injuries that required medical treatment and incurred medical and hospital expenses.

WHEREFORE, Plaintiffs demand judgment against Defendants for compensatory, statutory and punitive damages, together with interest, costs of suit, treble damages, attorneys'

fees and all such other relief as the Court deems appropriate pursuant to the common law and statutory law.

AS AN ELEVENTH CAUSE OF ACTION:
FRAUD BY CONCEALMENT

128. Plaintiffs incorporate by reference all other paragraphs of this complaint as if fully set forth and further alleges as follows:

129. Defendants had a duty and obligation to disclose to Plaintiff Kelli Baugh that the aforesaid product was dangerous and likely to cause serious health consequences to users when used as prescribed.

130. Defendants intentionally, willfully, and maliciously concealed and/or suppressed the facts set forth above from Plaintiff Kelli Baugh with the intent to defraud him as herein alleged.

131. Neither Plaintiff Kelli Baugh nor his physicians were aware of the facts set forth above, and had they been aware of said facts would not have prescribed this product.

132. As a proximate result of the concealment and/or suppression of the facts set forth above, Plaintiff Kelli Baugh has proximately sustained damage, as set forth herein.

133. As a direct and proximate result of one or more of these wrongful acts or omissions of the Defendants, Plaintiff Kelli Baugh suffered profound injuries that required medical treatment and incurred medical and hospital expenses.

WHEREFORE, Plaintiffs demand judgment against Defendants for compensatory, statutory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems appropriate pursuant to the common law and statutory law.

AS A TWELTH CAUSE OF ACTION:
JOINT & SEVERAL LIABILITY

134. Plaintiffs incorporate by reference all other paragraphs of this complaint as if fully as set forth and further alleges as follows:

135. Each of the Defendants named herein acted jointly and severally in all acts and omissions described herein and should therefore be held jointly and severally liable.

WHEREFORE, Plaintiffs demand judgment against Defendants for compensatory and punitive damages, together with interest, costs of suit, attorney's fees and such other relief as the Court deems appropriate pursuant to the common law and statutory law.

AS A THIRTEENTH CAUSE OF ACTION:
LOSS OF CONSORTIUM AND HOUSEHOLD SERVICES CLAIMS

136. Plaintiffs incorporate by reference all other paragraphs of this complaint as if fully set forth, and further allege as follows:

137. Plaintiff Justin Baugh is the husband of Kelli Baugh. The couple has two children and wanted to have a large family.

138. As a result of the medical conditions developed by his wife and the medical treatment and hospitalizations that she endured, Plaintiff Justin Baugh:

a. Lost a substantial measure of his wife's household services;

b. has lost, and will continue to lose in the future, a substantial measure of his wife's consortium,

c. has lost the opportunity to have additional children and add to his family with his wife.

139. As a direct and proximate result of one or more of these wrongful acts or omissions of the Defendants, Plaintiff Justin Baugh suffered injuries.

WHEREFORE, Plaintiffs demand judgment against Defendants for compensatory, statutory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems appropriate pursuant to the common law and statutory law.

REQUEST FOR PUNITIVE DAMAGES

140. Plaintiffs incorporate by reference all other paragraphs of this complaint as if fully set forth, and further alleges as follows:

141. At all times relevant herein, Defendants:

a. knew that Mirena was dangerous and ineffective;

b. concealed the dangers and health risks from Plaintiff Kelli Baugh, physicians, pharmacists, other medical providers, the FDA, and the public at large;

c. made misrepresentations to Plaintiff Kelli Baugh, his physicians, pharmacists, hospitals and medical providers and the public in general as previously stated herein as to the safety and efficacy of Mirena;

d. with full knowledge of the health risks associated with Mirena and without adequate warnings of the same, manufactured, marketed, promoted, developed, sold and/or distributed Mirena for routine use.

142. Defendants, by and through officers, directors, managing agents, authorized sales representatives, employees and/or other agents who engaged in malicious, fraudulent and oppressive conduct towards Plaintiff Kelli Baugh and the public, acted with willful and wanton and/or conscious and reckless disregard for the safety of Plaintiff Kelli Baugh and the general public.

143. As a direct and proximate result of one or more of these wrongful acts or omissions of the Defendants, Plaintiff Kelli Baugh suffered profound injuries that required medical treatment and incurred medical and hospital expenses, for which Plaintiff has become liable.

WHEREFORE, Plaintiffs demand judgment against Defendants for compensatory, statutory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems appropriate pursuant to the common law and statutory law.

PRAYER FOR RELIEF

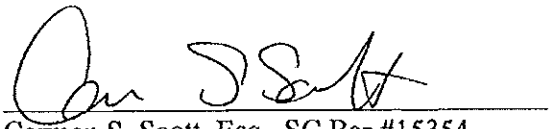
Plaintiffs demand judgment against Defendants for compensatory, statutory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems appropriate pursuant to the common law and statutory law.

JURY DEMAND

A jury trial is requested.

Respectfully submitted.

MOTLEY RICE LLC



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